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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,036	02/18/2004	Robert Belly	VDX-5001 USNP	3966

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EXAMINER	
DRODGE, JOSEPH W	
ART UNIT	PAPER NUMBER
1723	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,036	BELLY ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7,8 and 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Spelsberg patent 4,307,846 in view of Emanuel et al patent 2,928614, Murphy et al patent 5,374,522, Hoon et al patent 6,057,105 and Basset et al patent 5,484,726 (Emanuel and Basset being newly cited).

Spelsberg discloses a method for disrupting cells or tissue comprising placing samples comprising eukaryotic cells/tissue of various types in a container (12), adding a solution to the cells/tissue (column 4, line 49), placing a disruption element 38 having an outer dimension that is only slightly smaller than the inside dimension of the container into the container (column 4, lines 20-27), employing the disruption element over a very short time period (column 6, lines 27-37), removing cellular debris and unwanted materials from the sample, then extracting desired substance such as nuclei from the sample-containing solution, wherein there is contact between the disruption element and inner surface of container consisting essentially of a rotating-type rolling contact as the disruption element rotates around the container (column 5, lines 10-15, ***also see figure 1 and column 4, lines 44-50***).

The claims firstly differ in requiring that the solution comprise a nucleic acid-stabilizing solution. However, Basset et al teach such solution at column 28, lines 50-67 for extracting of nucleic acids from cell tissue, as does Hoon at column 32, lines 32-56. It would have been obvious to one of ordinary skill in the arts to have utilized a nucleic-acid type stabilizing solution in the Spelsberg process, as taught by Hoon and Basset, in order to preserve nucleic acid material, such as RNA, and to prevent decay, or changes in the nuclei, until metabolic testing can be completed.

The method claims also differ in requiring the disruption element for 45 seconds or less, although Spelsberg discloses that disruption and cell separation can occur rapidly or speedily, and at many times the rate of "prior art disruption processes (column 6, lines 30-37). Emanuel represent the "prior art" referred to by Spelsberg (tissue

homogenizer) and teaches a similar type of method of disrupting cells to isolate nuclei, involving a piston of diameter slightly smaller than a container, which is effective for disrupting cell tissue in a matter of 2-3 minutes (column 4, lines 30-34). Thus, it would have been obvious to one of ordinary skill in the art to have operated the Spelsberg disruption or during a time period of 45 seconds or less, so as to enable rapid or speedy processing of cell tissue and the processing of a greater total volume/quantity of cell tissue over time, and also enable concentration/extraction of nuclei while still metabolically active to enable accuate analysis of the nuclei.

The claims finally and thirdly, differ in requiring a step of decanting supernatant from the container prior to, or while extracting RNA from the decanted supernatant. Murphy discloses lysing or disrupting issues or cells that are in a container with disruption elements, (Abstract, column 14, lines 42-65, etc.), followed by removing DNA or RNA from other cellular debris by decantation and other separation steps, to extract the RNA from the sample (column 10, lines 52-65). It would have been obvious to one of ordinary skill in the art to have augmented the Spelsberg method by utilizing the decantation of Murphy, so as to effectively remove particulate debris from the cellular material being disrupted. It would also have been obvious to have extracted specifically RNA, as a nucleic acid material of interest, in view of Murphy, Hoon and Basset, since RNA is readily adaptable for histologic evaluation, in situ hybridididization experiments and for other analytical procedures to determine the presence and extent of growth of cancerous or other diseased cell tissues.

Regarding claims 8 and 16, both Hoon and Basset teach the sample being obtained from the patient during the course of a surgical procedure and cell tissue containing RNA being extracted from lymph node tissue (Hoon at column 32, lines 32-46 and Basset at column 28, lines 51-67). It would have been further obvious to one of ordinary skill in the art to have sampled tissue obtained during patient surgery, as suggested by Hoon and Basset, to facilitate timely diagnosis and treatment of diseases such as cancer.

Applicant's arguments filed on 17 January 2007 have been fully considered but they are not persuasive. It is argued that Spelsberg causes disruption by sliding moting of pestle member instead of rolling contact between pestle disruption element and container. However, Spelsberg discloses in figure 1, column 4, lines 42-65 and column 5, lines 45-50 that the pestle member rotates around the axis of a shaft as it contacts tissue being disrupted between circumferential outer surface of pestle and container. It is stated that since the entire cylindrical surface is in contact with the container, that the contact is a "sliding contact". However, "rolling contact" is understood to read on any surface that moves along a surface (here, the inner surface of the container) as it revolves on an axis. Neither contact that is "intermittent" or rotation in the manner of a rolling ball is required to anticipate the claim language.

It is argued that neither Spelsberg or Emanuel teaches decanting supernatant "from a worked sample". However, it is Murphy not Emanuel, especially column 10, lines 52-65 therein, that concern decanting. In reply to assertions that Murphy is not pertinent or combinable with Spelsberg, both references are commonly concerned with disruption of cellular tissue containing disease material from humans.

It is argued that Bassett does not teach the requirement to use a nucleic-acid-stabilizing solution, instead freezing tumor samples in liquid nitrogen until RNA is extracted. Such "RNA" extraction is understood as referring to any process that would separate RNA from other material of cellular tissue such as by cell disruption. The "liquid nitrogen" thus would be present when such RNA extraction occurs.

It is generally argued that the combination of references is improper due to varying techniques and equipment employed in them for disrupting cell tissue. However, all of the applied prior art commonly homogenizes and disrupts cell tissue for analysis of nucleic acid cell material and has common goals of conducting the sample disruption and analysis preparation in a rapid and accurate manner and achieving extraction of RNA or other nucleic acid sample extracts enabling rapid and accurate analysis of disease conditions.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve Griffin, can reached at 571-272-1189. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD
March 5, 2007

Joseph Drodge
Primary Examiner